MILITARY MEDICINE, 174, 12:1276, 2009

The Effectiveness of Acupuncture for Chronic Daily Headache: An Outcomes Study

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ABSTRACT With the increased incidence of migraine headaches noted in the military population it becomes imperative to find safe and effective treatment options for soldiers. Acupuncture may be one of those options. This pilot study used a standardized set of well-known acupuncture points over a predetermined time interval on 26 subjects suffering from chronic daily headache, the majority being migraineurs, and found a reduction in the frequency and intensity of their headaches. Headache calendars and validated measurements were compared 12 weeks before and 12 weeks after the acupuncture intervention. Results showed continued improvements 12 weeks after the last treatment. Traditionally, acupuncture treatments are individualized at each visit. However the absence of a standardized treatment regimen obstructs data reproducibility across the discipline. A standardized approach may be useful. Variations of these acupuncture points have been used in recent research studies for migraines and acupuncture for headaches for the past 2,000 years.

INTRODUCTION

Migraine headaches remain a common, but underdiagnosed and undertreated neurologic condition, affecting 6% of men and 15% of women in the general population.[1–3] Migraine headaches may be more prevalent in active duty soldiers, affecting 17.4% of men and 34.9% of women in one recent study.[4] The burden of headache is impacted by health care utilization, missed workdays, and lost productivity.[6] The American Migraine Study II reports 31% of headache respondents miss work, and productivity is reduced by half.[3] Increased sick call visits and impaired duty performance because of migraines was noted in surveyed U.S. Army soldiers returning from recent combat.[4]

Chronic daily headache (CDH) is frequently diagnosed in large tertiary care centers, defined as lasting more than 4 hours and occurring at least 15 days/month. CDH is estimated to affect 5% of the general population,[7] with an estimated cost burden of $420 million for health care utilization and $5.46 billion for lost workdays and reduced efficiency per year.[5] In a combat theater, physical and psychological stresses such as disrupted sleep and meal patterns trigger migraines in susceptible individuals.[4] Most patients suffer in silence and do not consult a physician for headaches because of low expectations of treatment benefits, history of unsatisfactory results, side effects of medications used in the past, or suboptimal treatments.[1]

As an alternative to traditional treatment, acupuncture is one of the more commonly researched and widely accepted complementary and alternative medicine (CAM) therapies in the treatment of migraines.[7–10] One study reported the use of acupuncture in the health care of sailors, Marines, and soldiers.[11] Currently, acupuncture is used for pain management and other conditions at U.S. military medical treatment facilities such as Andrews Air Force Base, MD, Walter Reed Army Medical Center, and Keesler Air Force Base, the Pentagon, Washington D.C., Luke Air Force Base, Scott Air Force Base, Travis Air Force Base, and at the Naval Medical Center San Diego, CA. Colonel (Dr.) Richard Niemtzow, U.S. Air Force, instructs other physicians on the use of ear and scalp acupuncture to reduce pain associated with battlefield wounds.[12]

Information on acupuncture research methodology is limited. Needling techniques, background of acupuncturists, length or duration of treatment, and appropriate control interventions are seldom described in acupuncture headache research.[9,13,14] In addition, the absence of standardized approaches to acupuncture treatments obstructs data reproducibility across the discipline. With this in mind, the goal was to use a Western approach to evaluate an effective standardized acupuncture treatment for CDH, replicable by both medical and traditional Chinese Medicine (TCM) trained practitioners.

Acupuncture studies developed according to TCM have reported the effectiveness of a semistandardized point combination in the treatment of migraines. No studies were found utilizing acupoints that did not vary from person to person or from treatment to treatment.

TCM explains the theory of acupuncture efficacy as a balance of yin and yang, which may loosely compare to the parasympathetic and sympathetic systems. Acupuncture meridians traverse all parts of the body and qi or energy course through these meridians. Imbalanced or blocked qi causes pain and dysfunction, and acupuncture may correct imbalance of flow through the meridian. For a review or deeper understanding of TCM concepts, refer to the National Institutes of Health

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Both authors have nothing to disclose and have no financial interests associated with this study. The views expressed in this manuscript are those of the authors and do not reflect the view of Memorial Medical Center or the official policy of the Department of Army, Department of Defense, or U.S. Government.

This manuscript was received for review in February 2009. The revised manuscript was accepted for publication in August 2009.

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
AUG 2009		**00-00-2009 to 00-00-2009**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
The Effectiveness of Acupuncture for Chronic Daily Headache: An Outcomes Study	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) **John P. Muriha Neuroscience and Pain Institute,1450 Scalp Ave., Suite 120,Johnstown,PA,15904**	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
see report

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT **unclassified**	b. ABSTRACT **unclassified**	c. THIS PAGE **unclassified**	**Same as Report (SAR)**	**7**	

consensus statement on acupuncture[14] or the textbook *Chinese Acupuncture and Moxibustion*.[18]

A review of acupuncture literature reveals a number of effective and frequently used acupuncture points for headache.[9,13,18] From this group, 4 points were chosen, located on distal extremities; 1 at the web space between the thumb and forefinger, 1 proximal to the wrist, and 2 points on the feet (Fig. 1). These points carry a low risk of penetrating vital organs and are easily accessible for electrical tonification, especially for acupuncture naive subjects. They can also be used during an acute headache episode without aggravating symptoms.

Most of the meridians are named for organs in the body but do not translate to their function according to conventional medicine. The first 2 points are located on the forearm and hand and are needled bilaterally. The first point, large intestine (LI) 4, is located on the back of the hand, between thumb and index finger. The second point, triple heater (TH) 5, is located on the back of the forearm (1–2 inches) proximal to the crease of the wrist.[15]

The last 2 points are located on the feet, also punctured bilaterally. Liver (LV) 3 is located on the top of the foot, in the web space between the first and second toes. The last acupuncture point is gall bladder (GB) 41, located between the fourth and fifth toes, lateral to the tendon.[15]

METHODS

Before recruitment, the Memorial Medical Center Institutional Review Board in Johnstown, Pennsylvania approved this study. Subjects were recruited from the local neuroscience and pain clinic, Family Medical Center, Internal Medicine clinic, and primary care offices served by the Conemaugh Health System. Self-referred subjects were recruited from the local community through media advertisements and flyers soliciting research participants.

Patients continued to use any previously prescribed headache medications or over-the-counter (OTC) medications as needed, and these were documented daily throughout the course of the study. Acupuncture was performed in 30-minute sessions twice a week for 4 weeks, followed by once a week for 4 weeks. A licensed physician medical acupuncturist with 300 hours of training from the Helms Medical Institute University of California, Los Angeles School of Medicine and 2 years of clinical acupuncture experience administered all acupuncture treatments.

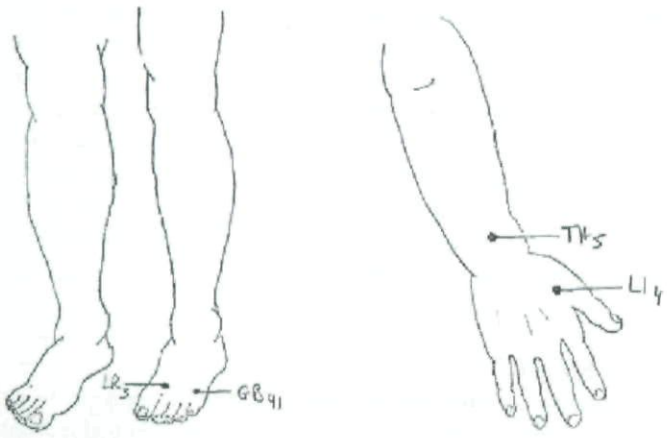

FIGURE 1. Acupuncture points.

The study began in June of 2005 and ended in November of 2006. All subjects began the study by completing a set of outcome measures; the Migraine Disability Assessment (MIDAS), Headache Impact Test (HIT-6), Medical Outcomes Study short form (SF-36), and Beck Depression Inventory (BDI-II). Subjects recorded daily headache activity on paper calendars for 12 weeks before the acupuncture intervention. Daily calendar entries included: frequency of headache attacks; severity, assessed using a visual analog scale (VAS) from 0 to 10 (0, no headache pain; 10, most severe headache pain experienced), and duration. Subjects also recorded the name and number of rescue medications taken, both over the counter and prescription. After successfully completing 12 weeks of headache calendars, subjects completed a second set of outcome measurements (MIDAS, HIT-6, SF-36, BDI-II) to establish a baseline pattern before beginning the acupuncture intervention.

Each subject was placed supine on the exam table. Pillows were placed under the head and knees, to make the subject comfortable, to help them remain in one position for the duration of the treatment. Eight sterile, disposable, steel acupuncture needles (Seirin Company, number 5 gauge [0.25] by 40 mm) were carefully placed bilaterally in the 4 standardized acupuncture points.

Acupuncture needles were tapped into place through sterile plastic guide tubes. The needle was slowly advanced until the subject felt "deqi" (a deep ache, warmth, tingling, pressure, or radiation). Mild electrical tonification was applied to the 2 acupuncture needles in the foot, using an ITO-IC-1107 + 3 channel transcutaneous electrical nerve stimulator (TENS) units. The negative or black lead was clipped onto the needle inserted at acupuncture point LV-3 and the positive lead was carefully clipped onto the GB-41 needle. Tonification was slowly increased to 1–3 Hz, until the subject felt a tapping or pulsing sensation and continued for exactly 20 minutes. As discussed earlier, the purpose of stimulation is to move energy through meridians. Each subject was supervised during every session by placing a baby monitor in the room. If a subject required adjustment of the stimulator or was in any distress, he or she could be heard by the acupuncturist, who would then return to the room to make any necessary adjustments. Subjects were free to discontinue treatments at any time, for any reason.

Subjects continued to maintain daily headache calendars throughout the 8 weeks of acupuncture and for an additional 12 weeks after their last acupuncture session. Subjects returned for a final assessment of outcome measures at the end of these 12 weeks. The outcome measures (MIDAS, HIT-6, SF-36, and BDI-II) were assessed at baseline or 12 weeks before intervention, immediately before and after acupuncture intervention, and at 12 weeks after the last acupuncture treatment.

A paired samples *t*-test with baseline mean versus end of treatment (EofT), 1 month following EofT, 2 months and 3 months following EofT was used for statistical analysis. Subjects kept a daily diary of perceived pain via VAS scales for 90 days before beginning the acupuncture intervention. The mean score of pain for these subjects was used as a stable baseline measure. As pain can be variable on a day-to-day basis, 90 days of pain assessment provided a more sound basis to assess improvement following treatment.

RESULTS

Fifty-four subjects with a diagnosis of chronic daily headache were screened and consented from the surrounding community. Of those 54 subjects consented, 37 were able to meet the inclusion and exclusion criteria listed in Table I. Of the 17 excluded subjects, 13 did not have a diagnosis of CDH, and 4 did not complete the necessary paperwork. Of the 37 subjects who met the inclusion/exclusion criteria, 26 subjects completed the study, 3 were lost to follow-up, and 8 dropped out. The reasons for dropout were as follows: One subject had a worsening of headache pattern after the first acupuncture intervention. One had worsening of fibromyalgia pain after 4 weeks of intervention, no change in headache pattern. One subject had continued leg cramps during acupuncture, which was not a new finding. One subject did not like the feeling of acupuncture sensation when accessing deqi. Four subjects had scheduling and work conflicts and were not able to complete the required visits.

Ages ranged from 27 to 65 with a mean of 46, with 21 female and 5 male subjects. Duration of headaches ranged from 1 to 54 years. Although all 26 subjects had a diagnosis of CDH, 25 had migraines and only 1 had CDH not the result of migraine. Three subjects had tension headaches, in addition to migraines. Two subjects had a history of spinal cord injuries, 1 had a history of brain tumor, and 1 had a history of head injury. Significant other comorbidities for this study were hypertension, hypothyroid, fibromyalgia, TMJ, and ankylosing spondylitis. Only 1 subject reported a history of depression.

TABLE I. Inclusion/Exclusion Criteria

Inclusion Criteria
Subjects between 21 and 65 years of age
6-month history of headaches
15 discrete headaches in a 31-day period
HIS diagnostic criteria for CDH
Subject had not received acupuncture for any medical condition in prior 12 months
Exclusion Criteria
Subject planned to receive acupuncture for another medical condition while enrolled in study
Organic pathology as cause of headache
Start of a new headache treatment less than 2 weeks before the proposed enrollment date
Systemic disorder or illness, including serious psychiatric illness
Pregnancy, lactation, or planned to become pregnant within 6 months
Regular use of alcohol or other recreational drugs
Cardiac pacemaker or other implanted electronic devices

Average VAS pain scores for all 26 subjects are described in Figure 2. VAS pain scores listed at baseline are 90-day average scores before intervention (preacupuncture). On the last day of acupuncture or end of treatment (EofT), a 5-day headache average was calculated and compared to the baseline average. Subsequent 5-day averages were completed at 1 month, 2 months, and 3 months postintervention. The *P*-value did not show any statistically significant change, meaning average pain scores remained stable 3 months after acupuncture intervention. The effects of pain reduction in these chronic daily headache subjects remained below baseline levels 12 weeks after the last acupuncture treatment.

The MIDAS is a 7-item questionnaire, measuring the effect of headache on activity and productivity. Subjects recorded the number of days missed for paid and nonpaid activities as well as days of decreased efficiency during a 3-month period. Average pain level over the preceding 3 months is also recorded. The graph shown in Figure 3 depicts how many days a headache impacted activity and productivity. Scores compared before and after acupuncture intervention improved significantly. The HIT-6 measures the degree to which headache impacts a person's job, school, home, and social situations. Figure 4 compares the HIT-6 questionnaire scores before and after acupuncture intervention showing improvement.

An association exists between frequent headaches and symptoms of depression.[19] Soldiers who have frequent migraines are more likely to have an increase incidence of depression.[4] Figure 5 shows a graph of the results from the BDI-II, scores taken before, after, and 12 weeks postacupuncture intervention showing improvements. The SF-36 is an appraisal of disease influence on well-being and functional status. When SF-36 measurements were taken immediately before acupuncture intervention and compared to those measurements taken at the end of the study or12 weeks after the last acupuncture treatment, improvement was found in 5 of the 8 areas. Quality of life (QOL) improved in this study population after an 8-week intervention of acupuncture.

Expected or anticipated adverse events or side effects were listed as pain, bruising, or bleeding at the acupuncture site, nausea, vomiting, lightheadedness, fatigue, or anxiety. Out of 312 visits and 2,496 punctured sites, adverse events were minimal. Pain, bruising, and bleeding occurred 19 times, with one incidence being listed as severe. Nausea occurred after 7 visits; none were recorded as severe. Fatigue and anxiety were reported 10 times. Insomnia, asthma, and worsening of depression were each recorded once. All adverse events received appropriate follow-up.

COMMENTS

The purpose of this study was to evaluate whether a set group of acupuncture points, delivered over a predefined period of time, would influence frequency, duration, and intensity

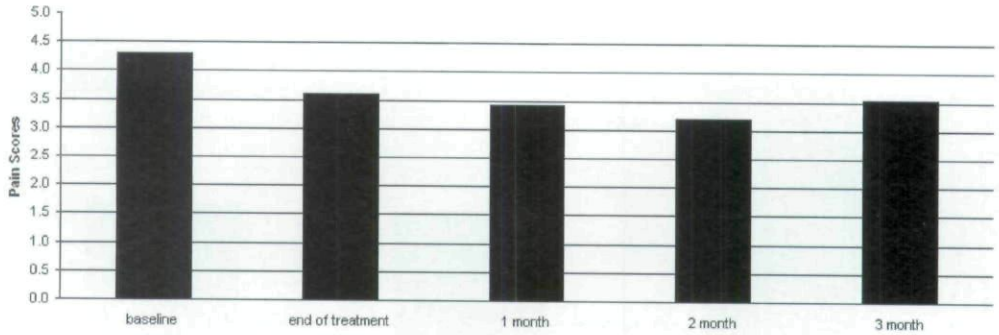

FIGURE 2. VAS pain scales over length of study.

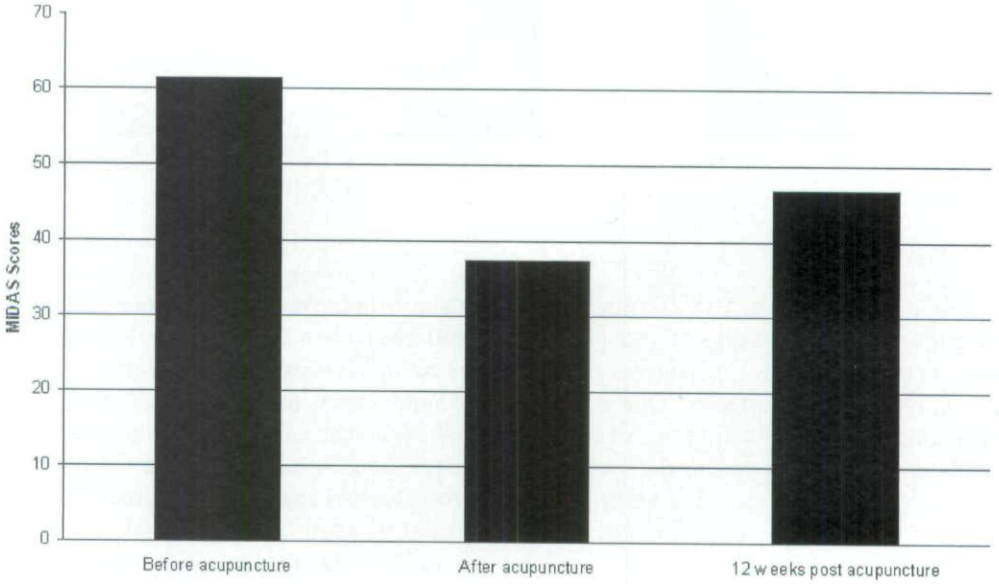

FIGURE 3. MIDAS scores before, after, and 12 weeks postintervention.

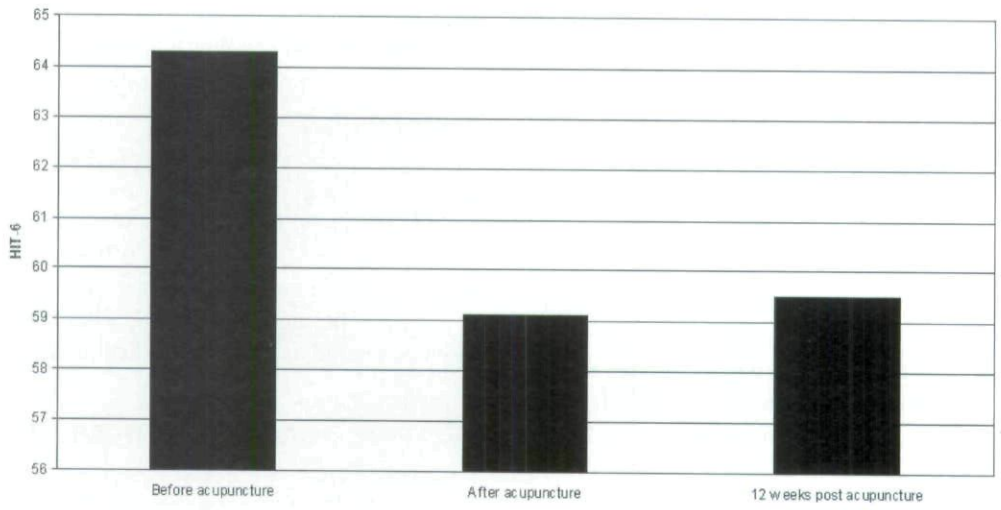

FIGURE 4. HIT measurement before, after, and 12 weeks postintervention.

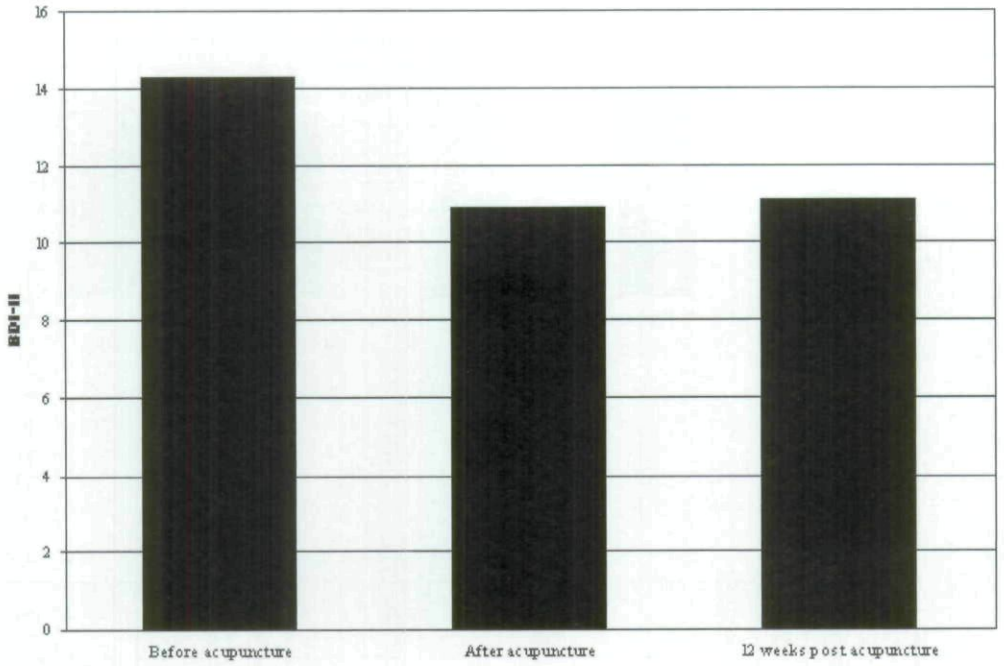

FIGURE 5. BDI-II before, after, and 12 weeks postintervention.

of headaches in those subjects with an IHS classification of CDH. Despite a small sample size, 8 weeks of a standardized acupuncture intervention had a positive influence on the frequency, duration, and intensity of headaches. One important finding was the reduction in pain scores after the acupuncture intervention, a trend that continued to decline for 8 weeks. At 12 weeks, pain scores began to rise again but never reached baseline levels. Monthly acupuncture maintenance treatments might prevent this rise, pending future acupuncture studies.

Another finding was the improvements in validated headache measurements, MIDAS and HIT-6. Although MIDAS scores were measured in 2 data sets before and after acupuncture intervention, the only improvements were found when data acquired directly before and directly after acupuncture were compared. All other comparisons were not found to be significant.

The HIT-6, which measures how headaches affect a person's life, showed statistically relevant improvements at all comparisons of pre- and postintervention. When preacupuncture data sets (baseline and immediately before acupuncture) were compared to data acquired immediately after acupuncture and 12 weeks after the last treatment, improvements were seen comparing all time points.

Because depression is a key concern in this CDH population, as well as in the military, BDI-II results are particularly relevant. Only 1 subject documented a history of depression on the medical history intake form, but 7 subjects actually scored moderate to severe depression on the BDI-II. Scores showed improvement when any preintervention data sets (baseline or immediately before intervention) were compared to postintervention data sets (immediately after intervention or 12 weeks after the last acupuncture treatment) in any combination. Improvements in depression may be the result of less headache pain or the acupoints themselves, but improvements lasted for 12 weeks postintervention.

Pain support medication utilization, both prescription and OTC, was tracked throughout the trial by pill count. Subjects were required to use the same medications at baseline when they first presented to the clinic for inclusion into the study. Most commonly used OTC's were nonsteroidal anti-inflammatory drugs (NSAID) and Excedrin combinations, and triptans were the most common prescription medication. There was a reduction in pain medication utilization between baseline measures and end of treatment. Acupuncture did not produce a common drug curve of effectiveness once treatment was terminated. This means that in medication trials, headaches returned after the cessation of treatment. With acupuncture as an intervention, headaches did not return to baseline 12 weeks later.

CONCLUSION

Although this is an outcomes study with a small number of subjects, an acupuncture intervention for the management of chronic daily headache showed significant findings in the improvement of a number of variables. Pain, validated headache measurements, depression, and quality of life all improved. The incidence of side effects was low especially when compared to standard medical treatment.

ACKNOWLEDGMENTS

The authors acknowledge Dr. Lisa Pasierb for her editing expertise. Boss Research Consultant Group was consulted when necessary for advice post data collection. This study was conducted through the Henry M. Jackson

Foundation for the Advancement of Military Medicine with funding provided by the Department of Defense, Uniformed Services University, under protocol no. G192BR-C5.

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